

TruLab PCT Level 2

Order Information

Cat. No. 5 9980 99 10 046 Level 2 Kit size 3 x 1 mL

Intended Use

Assayed quality control to monitor the analytical performance of quantitative in vitro determination of procalcitonin (PCT) on automated photometric systems.

Description

TruLab PCT is a liquid stable, aqueous control.

Contains recombinant PCT and biological additives from bovine origin.

The control is used with the DiaSys test Procalcitonin FS.

Level 2 is in the pathological range.

Storage

The control, both opened and unopened, must be stored at 2 – 8°C. Avoid contamination and protect from light. Do not freeze.

Stability

Unopened: Up to the date of expiry indicated on the kit

Opened: 12 months

Proper storage and handling of this product must be observed.

Warnings and Precautions

1. Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of calibrators and controls.
6. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Preparation

The control is ready to use.

Materials Required

General laboratory equipment

Procedure

Please refer to the reagent package insert for instructions for use.

Target Value

The target value has been determined using the DiaSys test Procalcitonin FS, calibrated by DiaSys TruCal PCT calibrator set. Calibrator values have been made traceable to a commercially available test on Roche cobas e 411.

Target value may vary with reagents and methods used.

Value listed below is valid for the indicated lot only.

Each laboratory should establish corrective action in case of deviations in control recovery.

Literature

1. Stenman UH, Standardization of immunoassays, In: Price CP, Newman DJ, editors, Principles and practice of immunoassay, New York: Stockton Press; 1997, p. 243-68.
2. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L. editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
3. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington 2009 (HHS Publication No. [CDC] 21-1112).

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.



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	Lot No.	Expiry Date	Target Value	Range
TruLab PCT Level 2	35197	2024-11-02	10.3 ng/mL	8.22 – 12.3 ng/mL